IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Adam S. Cantor et al.	Art Unit	: 1615
Serial No.	: 09/965,610	Examiner	: Isis A. D. Ghali
Filed	: September 26, 2001	Conf. No.	: 8132

Title : COMPOSITION FOR TRANSDERMAL DELIVERY OF FENTANYL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Pursuant to 37 C.F.R. § 41.41, Appellants respond to the Examiner's Answer as follows.

1. On page 5 of the Examiner's Answer, under the section entitled "Applicant Claims," the Examiner states that the claims are directed to a transdermal drug delivery composition "comprising" certain ingredients. This is incorrect. The claims are directed to a transdermal drug delivery composition "consisting essentially of" certain ingredients. The distinction is important because the "consisting essentially of" language excludes ingredients that materially affect the novel properties of the composition—here, its drug delivery properties. Thus, it excludes the polysiloxanes in the amounts described in Miranda because Miranda expressly teaches that such amounts of polysiloxanes affect the drug delivery properties of the Miranda's composition.

2. On page 13 of the Examiner's Answer, the Examiner states:

> [I]t is argued that Miranda teaches polysiloxane in an amount that can be as low as 4%. In absence of definition of the expression "consisting essentially of" by appellants, the amount taught by Miranda can fall within the ingredients covered by the expression "consisting essentially of." As appellants themselves admit, polysiloxane taught by Miranda to affect the drug delivery properties and according to the desired drug delivery property, the polysiloxane can be diminished or increased according to the desired delivery characteristics. It has been held that omission of an element and its function is obvious if the function of the element is not desired.

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In this passage, the Examiner admits that Miranda describes including polysiloxane in an amount designed to affect the drug delivery properties of a transdermal drug delivery composition. The "consisting essentially of" language appearing in Appellants' claims necessarily excludes such amounts of polysiloxanes. Whether or not it would have been obvious to eliminate polysiloxane entirely, or to alter its amount in a given composition, is irrelevant to the issue of whether the "consisting essentially of" language in Appellants' claims excludes polysiloxanes in amounts designed to affect drug delivery properties of a transdermal drug delivery composition.

3. The Examiner does not dispute that the novel and material characteristics of a transdermal drug delivery composition relate to the drug delivery properties of the composition. The Examiner also does not dispute that Miranda requires including polysiloxane in a transdermal drug delivery composition in an amount purposefully selected to affect the drug delivery properties of the composition. Nevertheless, on pages 14-16 of the Examiner's Answer, the Examiner states:

> Appellants have not shown in the specification that polysiloxane would change the characteristic of their invention …. [A]bsent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."

The Examiner's position appears to be that unless Appellants' specification expressly recites a numerical threshold for polysiloxane, and further teaches that amounts above this threshold affect the drug delivery properties of the composition, she will not interpret the "consisting essentially of" language in Appellants' claims as excluding polysiloxanes in the amounts that Miranda requires because there is no evidence that such amounts of polysiloxanes will affect the drug delivery properties of the claimed compositions.

The Examiner's position is simply wrong. Miranda itself is the evidence that polysiloxanes in the amounts taught by Miranda affect the drug delivery properties of acrylate-containing transdermal drug delivery compositions. That is the whole reason why Miranda includes such amounts of polysiloxanes in the first place. It is irrelevant whether Appellants' specification expressly defines some numerical limitation for polysiloxane because there is no

requirement that it do so. The "consisting essentially of" language appearing in the claims is all that is needed. The Examiner is obligated to give this language weight.

4. On pages 15-17 of the Examiner's Answer, the Examiner reiterates her position that it would have been obvious to combine Garbe and Miranda because Garbe allegedly teaches that Miranda's polysiloxane can be eliminated altogether. The Examiner states:

> The claims' language and the present disclosure do not absolutely exclude polysiloxane of Miranda that is as low as 4%. Although Miranda anticipate the present claims and can stand by itself to render the claims obvious, however, Garbe shows that even 4% of polysiloxane of Miranda can be excluded from the polymer composition and may be replaced by macromer and still provide excellent drug dissolution …. The polymer composition taught by the combination of Miranda and Garbe does not necessarily contain polysiloxane.

The fact that Garbe describes an alternative composition that lacks polysiloxane does not give the Examiner license to ignore Miranda's express teaching that certain amounts of polysiloxane are critical and must be included. In particular, it does not allow the Examiner to rely on Miranda selectively for certain features, while ignoring Miranda's requirement that the compositions contain polysiloxane.

For these reasons, and the reasons stated in the Appeal Brief, Appellants submit that the final rejection should be reversed.

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Respectfully submitted,

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